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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,021	02/09/2005	Yoshiji Yamada	80174(302730)	3971
21874	7590	02/04/2009		
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KAPUSHOC, STEPHEN THOMAS				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
02/04/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,021

Applicant(s)

YAMADA ET AL.

Examiner

Stephen Kapushoc

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE-US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Please note that the Examiner handling this application has changed since the Office Action of 02/22/2008 and is now Stephen Kapushoc in Art Unit 1634.

Claim 20 is pending and examined on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/20/2008 has been entered.

This Office Action is in reply to Applicants' correspondence of 11/20/2008.

Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put this application in condition for allowance. New grounds of rejection are presented in this Office Action. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action.

This Action is **NON-FINAL**.

Claim Objections

1. Claim 20 is objected to because of the following informalities:

Claim 20 is object to over recitation of the phrase 'at polymorphisms (1), (2), and (3)' where the enumerated listing of claim 20 refers to alleles, and thus is not consonant with the objected to language. Further, as the claim requires the combination of all of

the three enumerated alleles, there is no need to enumerate the alleles and then define the enumerated content. Suggested claim language is provided later in this Office Action in the rejection of the pending claim under 35 USC 101.

Appropriate correction is required.

New Claim Rejections - 35 USC § 101 Non-Statutory Subject Matter

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 20 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The rejected claim is drawn to a method for determining an increased risk of restenosis after coronary angioplasty. The claimed invention falls within an enumerated statutory category, namely a process.

The rejected claim is drawn to a method for determining an increased risk comprising the steps of detecting nucleotide content and correlating detected content with risk of restenosis.

In re Bilski No. 2007-1130 (Fed Cir. October 30, 2008) characterizes its machine-transformation test as "the governing test for determining patent eligibility of a process under section 101." Under this test, a process claim is patent-eligible if (and, as applied in Bilski, only if): "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." The claims are not directed to patent-

eligible subject matter since they are not tied to any particular machine or apparatus and they do not require any particular article to be transformed into another state or thing.

The rejected claim does not require the transformation of an article or physical object to a different state. For example, relevant to the rejected claims, one could detect genotypes *in silico* by consulting a digital record in an electronic database of nucleic acid sequence information previously derived during a genome sequencing project, and further correlate genotype to risk *in silico* using an algorithm. In fact the instant specification teaches the analysis of databases for the identification of polymorphic sites (e.g.: p.3 Ins.14-15). Additionally, there is no result tied to the physical world. There is no required transformation of an article or physical object to a different state. Transformation of data is not considered a physical transformation.

As clearly noted in *In re Comiskey No. 2006-1286* (Fed. Cir. Sept. 20, 2007), "the Supreme Court has reviewed process patents reciting algorithms or abstract concepts in claims directed to industrial processes. In that context, the Supreme Court has held that a claim reciting an algorithm or abstract idea can state statutory subject matter only if, as employed in the process, it is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, i.e., a machine, manufacture, or composition of matter. 35 U.S.C. § 101." Regarding *In re Comiskey*, the USPTO noted, "[t]he Supreme Court has recognized only two instances in which such a method may qualify as a section 101 process: when the process 'either [1] was tied to a particular apparatus or [2] operated to change materials to a 'different state or thing.'"" (quoting

Flook, 2006-1286 17 437 U.S. at 588 n.9). In Diehr, the Supreme Court confirmed that a process claim reciting an algorithm could state statutory subject matter if it: (1) is tied to a machine or (2) creates or involves a composition of matter or manufacture. 450 U.S. at 184. There, in the context of a process claim for curing rubber that recited an algorithm, the Court concluded that "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." *Id.* (quoting *Benson*, 409 U.S. at 70);¹³ see also *In re Schrader*, 22 F.3d 290, 295 (Fed. Cir. 1994) (holding when a claim does not invoke a machine, "§ 101 requires some kind of transformation or reduction of subject matter").

Finally, the *Comisky* opinion states that mental processes- or processes of human thinking- standing alone are not patentable even if they have practical application. The Supreme Court has stated that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Benson*, 409 U.S. at 67. In *Flook* the patentee argued that his claims did not seek to patent an abstract idea (an algorithm) because they were limited to a practical application of that idea-updating "alarm limits" for catalytic chemical conversion of hydrocarbons. 437 U.S. at 586, 589-90. The Court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that "[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula." *Id.* at 590.

In the case of the instantly rejected claims, there is no recitation of producing a real-word result that is tied to a machine or apparatus or causes a transformation of an article. In other words, the outcomes of the rejected methods lack a tie to the machine or apparatus and lack a physical transformation. Thus the claim is rejected as encompassing non-statutory subject matter.

The claims may be drawn to statutory subject matter if the methods are amended to specifically require the steps of, for example, obtaining a biological sample, and detecting particular nucleotide content in the sample. For example:

A method for determining an increased risk of restenosis after coronary angioplasty in a Japanese man, said method comprising:

(i) obtaining a biological sample from said Japanese man, said sample comprising nucleic acids from said Japanese man;

(ii) detecting in said nucleic acids a C at position 3932 of SEQ ID NO: 1 in at least one allele of the apolipoprotein E gene, an A at position 197 of SEQ ID NO: 3 in at least one allele of the tumor necrosis factor- α gene, and a T at position 831 of SEQ ID NO: 4 in both alleles of the G-protein β 3 subunit gene; and

(iii) correlating a C at position 3932 of SEQ ID NO: 1 in at least one allele of the apolipoprotein E gene, an A at position 197 of SEQ ID NO: 3 in at least one allele of the tumor necrosis factor- α gene, and a T at position 831 of SEQ ID NO: 4 in both alleles of the G-protein β 3 subunit gene in said nucleic acids with an increased risk of restenosis after coronary angioplasty in said Japanese man.

Withdrawn Claim Rejections - 35 USC § 112 – 2nd ¶ - Indefiniteness

4. The rejections of claims under 35 USC 112 2nd ¶, as set forth on pages 2-3 of the previous Office Action of 02/22/2008 are **WITHDRAWN** in light of the amendments to the claims.

Withdrawn Claim Rejections - 35 USC § 112 – 1st ¶ - Scope of Enablement

5. The rejection of claims under 35 USC 112 1st ¶ for encompassing non-enabled scope, as set forth on pages 3-12 of the previous Office Action of 02/22/2008 are **WITHDRAWN** in light of the amendments to the claims. It is noted that while there is unpredictability with regard to the association of the nucleic acid positions recited in the claims and restenosis in women (as demonstrated by Fig 9 and 11 of the instant specification) and in non-Japanese populations (as demonstrated by von Beckerath et al (2000), Koch et al (2003), and Samani et al (1996), the claims are limited to Japanese males, which is enabled by the instant specification (Fig 8, 10, 12, and 13).

Conclusion

6. The claim is not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Stephen Kapushoc/

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